



Food and Drug Administration  
10903 New Hampshire Avenue  
Document Control Room – WO66-G609  
Silver Spring, MD 20993-0002

JUN 25 2010

Mr. Patrick Leong  
Chief Operation Officer  
Tekmedic (M) SDN BHD  
Plot 4, Tanjung Kling Industrial Area  
Jetty, Tanjung Kling, Melaka  
MALAYSIA

Re: K100694

Trade/Device Name: Colored Powder Free and Polymer Coated Latex Examination Glove  
(Blue, Black and Pink) with a Protein Claim of Less than 50 µg/gm Glove  
Regulation Number: 21 CFR 880.6250  
Regulation Name: Patient Examination Glove  
Regulatory Class: I  
Product Code: LYY  
Dated: June 9, 2010  
Received: June 16, 2010

Dear Mr. Leong:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

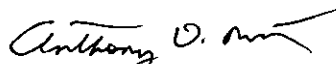
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to <http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm> for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to <http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address <http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,



Anthony D. Watson, B.S., M.S., M.B.A.  
Director

Division of Anesthesiology, General Hospital,  
Infection Control and Dental Devices  
Office of Device Evaluation  
Center for Devices and  
Radiological Health

Enclosure

*Premarket Notification For Colored Powder Free And Polymer Coated Latex Examination Glove (Blue, Black and Pink) With A Protein Claim Of Less Than 50µg/dm<sup>2</sup>*

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**3.0 Indications For Use Statement**

510(K) Number (if known): K100694

Device Name: Colored Powder Free And Polymer Coated Latex Examination Glove (Blue, Black and Pink) With A Protein Claim Of Less Than 50 µg/gm Glove

Indications For Use : A colored, powder free and polymer coated latex examination glove is a disposable device made of natural latex that may bear a trace amount of glove powder and is intended to be worn on the hands or finger(s) for medical purposes to provide a barrier against potentially infectious materials and other contaminants. A color, blue, black or pink will be added to the latex examination glove in the production process to produce the colored glove.

Prescription Use \_\_\_\_\_  
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use ☒  
(21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

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Concurrence of CDRH, Office of Division Sign-Off (ODE)

Steven T. L. for G. Jayan  
Division of Anesthesiology, General Hospital  
Infection Control, Dental Devices

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